



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/729,527  
Applicant : Williams  
Filed : December 5, 2003  
Title : SOLUBLE RECOMBINANT BOTULINUM TOXINS HAVING A C-  
TERMINAL PORTION OF A HEAVY CHAIN, A N-TERMINAL  
PORTION OF A HEAVY CHAIN AND A LIGHT CHAIN  
  
TC/A.U. : 1600/1645  
Examiner : PORTNER, V.A.  
  
Docket No. : D2939-CIPCONDIV3

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.	
Date:	<u>June 10, 2003</u>
By:	<u>Jaret McGree</u>

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

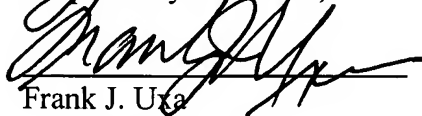
Dear Sir:

Applicant wishes to call to the attention of the Examiner the documents cited on the accompanying Form PTO-1449. The cited documents were either identified in one or more related applications or are applications related to the above-identified application. This communication is being submitted under 37 C.F.R. 1.97(c)(2). The Commissioner is hereby authorized to charge the necessary fee to Deposit Account No. 01-0885.

Each of these documents was cited in related (parent) application Serial No. 10/271,012 filed October 15, 2002. Therefore, no copies of these documents are submitted herewith. Applicant requests that each of these documents be made of record in the above-identified application.

Date: 6/10/05

Respectfully submitted,

  
Frank J. Uxa

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06/21/2005 HNGUYEN1 00000023 010885 10729527

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Form PTO-1449

# **INFORMATION DISCLOSURE CITATION IN AN APPLICATION**

(Use several sheets if necessary)

Docket No.: D2939-CIPCONDIV3

Application No.: 10/729,527

Applicant: Williams

Filing Date: December 5, 2003

Group Art Unit: 1645

## **U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,071,759	12/1991	Rothman et al.			
	5,196,193	03/1993	Carroll			
	5,268,295	12/1993	Serrero			
	5,310,663	05/1994	Dobeli et al.			
	5,410,019	04/1995	Coy et al.			
	5,565,334	10/1996	Kufe et al.			
	5,837,264	11/1998	Becker et al.			
	5,837,265	11/1998	Montal et al.			
	5,874,415	02/1999	Kufe et al.			
	5,891,842	04/1999	Kream			
	5,919,665	07/1999	Williams			
	5,939,070	08/1999	Johnson et al.			

## **FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	93/05800	04/1993	WO				
	94/13264	06/1994	WO				
	94/21684	09/1994	WO				
	95/32738	12/1995	WO				
	96/05222	02/1996	WO				

## **OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

AA	U.S. Application No. 08/704,159, filed 8/28/1996, Williams (Docket No. D2939-CIP)
AB	U.S. Application No. 10/271,012, filed 10/15/2002, Williams (Docket No. D2939-CIPCON)
AC	U.S. Application No. 10/728,696, filed 12/05/2003, Williams (Docket No. D2939-CIPCONDIV01)
AD	U.S. Application No. 10/729,122, filed 12/05/2003, Williams (Docket No. D2939-CIPCONDIV02)
AE	U.S. Application No. 10/729,039, filed 12/05/2003, Williams (Docket No. D2939-CIPCONDIV04)
AF	U.S. Application No. 11/001,241, filed 11/30/2004, Williams (Docket No. D2939-CIPCONCON)
AG	U.S. Application No. 10/354,774 filed 01/30/2003, Williams (Docket No. D2939-CIPCON2)
AH	U.S. Application No. 10/727,898, filed 12/04/2003, Williams (Docket No. D2939-CIPCON2DIV)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

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<b>U. S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	5,955,368	09/1999	Johnson et al.				
	6,022,950	02/2000	Murphy				
	6,287,566	09/2001	Dertzbaugh				
	6,545,126	04/2003	Johnson et al.				
	6,787,517	09/2004	Gil et al.				
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	EP 0 209 281	01/1987	Europe				
	EP 0 282 042	09/1988	Europe				
	EP 0 593 176	04/1994	Europe				
	GB 2 272 697	05/1994	Great Britain				
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	AI	Ford et al., (1991) Protein Expression & Purification, 2:95-107					
	AJ	Kimura et al., (1991) Applied & Enviro Microbio, 57(4):1168-72					
	AK	TaKaRa Shuzo Co. Catalog of TAKARA BIO INC at the web site: bio.takara.co.jp					
	AL	Nassau et al., (1996) J. Bacterio, 178(4):1047-52					
	AM	Hill et al., (1996) Arch. Biochem. and Biophys. 336(2):283-9.					
	AN	Crowe et al., (1994) Methods in Molecular Biology, 31:371-387.					
	AO	Maisey et al., (1988) Eur. J. Biochem 177:683-691					
	AP	Rudinger, J. in Peptide Hormones, Parsons, J.A. (Ed,) Univ. Park Press, Baltimore, MD pp. 1-7.					
	AQ	Roitt, I. Essential Immun., 6 <sup>th</sup> Edition, Blackwell Scientific Publications, Boston, MA, pp. 173-178.					
	AR	LeClerc, C. et al. J. Immunol. 144(8): 3174-3182					
	AS	Kleid, D.G. Annals NY Acad. Sci. 413:23-30.					
	AT	Siegel, L.J. Clin. Microbiol. 26: 2351-2356.					
	AU	Swiss-Prot Accession Number Q60393, Botulinum neurotoxin type G, Campbell, K et al (1993) cited therein.					
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EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2003/0049264	03/2003	Foster et al.			
	2003/0185850	10/2003	Dertzbaugh			
	5,601,823	02/1997	Williams et al.			
	5,814,477	09/1998	Williams et al.			
	6,573,244	06/2003	Gordon et al.			
<b>FOREIGN PATENT DOCUMENTS</b>						
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						YES      NO
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>						
	AV	Dertzbaugh, MT et al, Vaccine, Vol. 14(16), pages 1538-1544, 1996, Mapping of protective and cross-reactive domains of the type A neurotoxin of Clostridium botulinum.				
	AW	Beitle et al., "One-step purification of a model periplasmic protein from inclusion bodies by its fusion to an effective metal-binding peptide", Biotechnology Progress, Vol. 9, pp 64-69 (1993).				
	AX	Kamiya et al., "Production of Monoclonal Antibody to Clostridium Difficile Toxin A Which Neutralizes Enterotoxicity But Not Haemagglutination Activity", FEMS Microbiology Letters, Vol. 81, pages 311-316 (1991)				
	AY	Hatheway, "Toxigenic Clostridia", Clin. Microbiology Reviews, Vol. 3, No. 1, pages 66-98 (1990)				
	AZ	Coughlin et al., Characterization of six murine monoclonal antibodies specific for toxin B of Clostridium difficile", Hybridoma, Vol. 13, pages 147-152 (1994).				
	BA	Hochuli et al., "Generic approach to facilitate purification of recombinant proteins with a novel metal chelate adsorbent", Biotechnology, Vol. 6, pages 1321-1325 (1988).				
	BB	Lilius et al., "Metal affinity precipitation of proteins carrying genetically attached polyhistidine affinity tails", Eur. J. Biochem., Vol. 198, pages 499-504 (1991).				
	BC	Wiedemann et al., "Chicken egg antibodies for prophylaxis and therapy of infectious intestinal diseases", J. Vet. Med., Vol. 38, pages 283-291 (1991).				
	BD	Handl et al., High yield of active STb enterotoxin from a fusion protein (MBP-STb) expressed in E. Coli", Protein Expression and Purification, Vol. 4, pages 275-281 (1993).				
	BE	Von Eichel-Streiber et al., "Cloning of Clostridium difficile toxin B gene and demonstration of high N-terminal homology between A and B", Med. Microbiol. Immunol., Vol. 179, pp 271-279 (1990).				
	BF	Kim et al, Characterization of protective antibodies in hamsters immunized against Clostridium difficile toxins A and B", Microbial Ecology in Health and Disease, Vol. 2, pp 47-59 (1989).				
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	BG	Zhou et al., "Expression and Purification of the Light Chain of Botulinum Neurotoxin A: A single mutation abolishes its Cleavage of SNAP-25 and Neurotoxicity after reconstruction with the Heavy Chain", Biochemistry, Vol. 34, No. 46, pages 15175-15181 (1995)				
	BH	Clayton et al, "Protective vaccination With a Recombinant Fragment of Clostridium Botulinum Neurotoxin Serotype A Expressed from a Synthetic Gene in E Coli", Infection and Immunity, Vol. 63, No. 7, pages 2738-2742 (1995).				
	BI	Schiavo et al, "Tetanus and Botulinum-B Neurotoxins Block Neurotransmitter Release by Proteolytic Cleavage of Synaptobrevin", Nature, Vol. 359, pages 832-835 (1992)				
	BJ	Kriegelstein et al., J. Protein Chem. 1994 Jan; 13(1):49-57.				
	BK	Hutson et al., FEMS Microbiol Lett. 1993 Mar 15; 108(1):103-10.				
	BL	Szabo et al., Appl Environ. Microbiol, 1993, 59(9):3011-3020.				
	BM	Minton et al., "Host: Vector systems for gene cloning in Clostridium", Microbiological Sciences, 5(10):310-315 (1988).				
	BN	Jung et al, "Cloning of a Clostridium botulinum type B toxin gene fragment encoding the N-terminus of the heavy chain", FEMS Microbiol. Lett., 70(1):69-72 (1992).				
	BO	Campbell et al., "Gene Probes for Identification of the Botulinal Neurotoxin Gene and Specific Identification of Neurotoxin Types B, E, and F", Jour. Clin. Microbiology, Vol. 31, No. 9, pages 2255-2262 (1993).				
	BP	Hauser et al., "Nucleotide sequence of Clostridium botulinum C1 neurotoxin", Nucleic Acids Research, Vol. 18, No. 16, page 4924 (1990).				
	BQ	Mierendorf et al, "The pET System: Your choice for Expression", in Novations, Newsletter of Novagen, Inc., Vol. 1, No. 1, pp 1-3, May 1994.				
	BR	Moberg et al., "Affinity Chromatography Purification of Type A Botulinum Neurotoxin from Crystalline Toxin Complex", Applied and Environ. Microbiology, Vol. 35, No. 5, pp 878-880 (1978).				
	BS	Kimura K., English abstract: "The structure and function of botulinum type C neurotoxin", Hokkaido Igaku Zasshi [Article in Japanese], 1991 Nov; 66(6):841-8.				
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	BT	Aktories, K et al, Biochem. J. 1987, October 15, vol. 247(2) pages 363-368 (abstract only)				
	BU	Valderrama, F. et al, PNAS, Vol. 97(4) pages 1560-1565, February 15, 2000				
	BW	Poulain, B et al, Journal of Biological Chemistry, Vol. 264(36) issue of Dec. 25, pages 21928-21933, 1989.				
	BX	Sathyamoorthy, Venugopal et al, The Journal of Biological Chemistry, vol. 260(19) pages 10461-10466, Sept. 5, 1985.				
	BY	Pascchnik, VA et al, Bioseparation, Vol. 3, pages 267-283, 1993.				
	BZ	DiBello, Cenci et al., European Journal of Biochemistry/FEBS (Germany) January 15, 1994, Vol. 219(1-2), pages 161-169.				
	CA	Niemann, H. et al, Behring. Inst. Mitt. No. 89, pages 153-162, 1991.				
	CB	Fujii, N. et al, Appl. Environ. Microbiol., Jan. 1988, vol. 54(1), pages 69-73.				
	CC	Syuto, B. et al, Journal of Biological Chemistry, vol. 256(8) April 25, 1981, pages 3712-3717.				
	CD	Young, M. et al, FEMS Microbiology Reviews, Vol. 63, pages 301-325, December 1989.				
	CE	Kurazono (1992) Journal of Biological Chemistry, 267(21):14721-14729.				
	CF	Mochida (1990) PNAS (USA), 87:7844-8.				
	CG	Binz, T. et al., The Journal of Biological Chemistry, Vol. 266(16), pages 9153-9158, June 1990.				
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